General Assembly

Amendment

February Session, 2016

LCO No. **6168**

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Offered by:
REP. CARTER, 2nd Dist.

To: Senate Bill No. **309** File No. 170 Cal. No. 444

(As Amended by Senate Amendment Schedule "A")

"AN ACT ESTABLISHING A TASK FORCE TO STUDY VALUE-BASED PRICING OF PRESCRIPTION DRUGS."

After the last section, add the following and renumber sections and internal references accordingly:

"Sec. 501. Section 20-619 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2016*):

(a) For the purposes of section 20-579 and this section:

(1) "Biological product" has the same meaning as provided in 42 USC 262(i);

[(1)**]** (2) "Brand name" means the proprietary or trade name selected by the manufacturer and placed upon a drug product, its container, label or wrapping at the time of packaging;

[(2)**]** (3) "Generic name" means the established name designated in

the official United States Pharmacopoeia-National Formulary, official Homeopathic Pharmacopoeia of the United States, or official United States Adopted Names or any supplement to any of said publications;

(4) "Interchangeable" means, with respect to a biological product, a product that the federal Food and Drug Administration has: (A) Determined to be interchangeable, pursuant to 42 USC 262(k)(4), or (B) (i) determined to be therapeutically equivalent to another biological product, and (ii) granted an A rating as set for in the latest edition of the federal Food and Drug Administration's publication "Approved Drug Products with Therapeutic Equivalence Evaluations";

[(3)**]** (5) "Therapeutically equivalent" means drug products that are approved under the provisions of the federal Food, Drug and Cosmetic Act for interstate distribution and that will provide essentially the same efficacy and toxicity when administered to an individual in the same dosage regimen;

[(4)**]** (6) "Dosage form" means the physical formulation or medium in which the product is intended, manufactured and made available for use, including, but not limited to, tablets, capsules, oral solutions, aerosol, inhalers, gels, lotions, creams, ointments, transdermals and suppositories, and the particular form of any physical formulation or medium that uses a specific technology or mechanism to control, enhance or direct the release, targeting, systemic absorption, or other delivery of a dosage regimen in the body;

[(5)**]** (7) "Epilepsy" means a neurological condition characterized by recurrent seizures;

[(6)**]** (8) "Seizures" means a disturbance in the electrical activity of the brain; and

[(7)**]** (9) "Antiepileptic drug" means a drug prescribed for the treatment of epilepsy or a drug used to prevent seizures.

(b) Except as limited by subsections **[**(c), (e) and (i)**]** (e), (g) and (k) of

this section, unless the purchaser instructs otherwise, the pharmacist may substitute a generic drug product with the same strength, quantity, dose and dosage form as the prescribed drug product which is, in the pharmacist's professional opinion, therapeutically equivalent. When the prescribing practitioner is not reasonably available for consultation and the prescribed drug does not use a unique delivery system technology, the pharmacist may substitute an oral tablet, capsule or liquid form of the prescribed drug as long as the form dispensed has the same strength, dose and dose schedule and is therapeutically equivalent to the drug prescribed. The pharmacist shall inform the patient or a representative of the patient, and the practitioner of the substitution at the earliest reasonable time.

(c) Except as limited by subsections (e), (g) and (k) of this section, unless the purchaser instructs otherwise, the pharmacist may substitute a biological product for a prescribed biological product if: (A) The federal Food and Drug Administration has determined that the biological product to be substituted is interchangeable with the prescribed biological product, and (B) the practitioner has not specified, in the manner described in subsection (e) of this section, that there shall be no substitution for the prescribed biological product.

(d) The pharmacist shall inform the prescribing practitioner and the patient or a representative of the patient at the earliest reasonable time of the substitution of a biological product for a prescribed biological product.

[(c)**]** (e) A prescribing practitioner may specify in writing or by a telephonic or other electronic communication that there shall be no substitution for the specified brand name drug product or interchangeable biological product specified on any prescription form, provided (1) for written prescriptions, the practitioner shall specify on the prescription form that the drug product or interchangeable biological product is "brand medically necessary" or "no substitution", (2) for prescriptions transmitted by telephonic means, the pharmacist shall specify "brand medically necessary" or "no substitution" on the

prescription form in the pharmacist's handwriting or in the electronic prescription record and shall record on the prescription form the time the telephonic authorization was received and the name of the person who communicated the telephonic authorization to the pharmacist, and (3) for prescriptions transmitted by any other electronic communication, the practitioner shall select the dispense as written code on the certified electronic prescription form to indicate that a substitution is not allowed by the practitioner. No prescription form for written prescriptions, and no prescription form for prescriptions transmitted pursuant to subdivision (2) or (3) of this subsection, may default to "brand medically necessary" or "no substitution".

[(d)**]** (f) Each pharmacy shall post a sign in a location easily seen by patrons at the counter where prescriptions are dispensed stating that, "THIS PHARMACY MAY BE ABLE TO SUBSTITUTE A LESS EXPENSIVE DRUG PRODUCT OR INTERCHANGEABLE BIOLOGICAL PRODUCT WHICH IS THERAPEUTICALLY EQUIVALENT TO THE ONE PRESCRIBED BY YOUR DOCTOR UNLESS YOU DO NOT APPROVE." The printing on the sign shall be in block letters not less than one inch in height.

[(e)**]** (g) A pharmacist may substitute a drug product under subsection (b) or interchangeable biological product under subsection (c) of this section only when there will be a savings in cost passed on to the purchaser. The pharmacist shall disclose the amount of the savings at the request of the patient.

[(f)**]** (h) Except as provided in subsection **[**(g)**]** (i) of this section, when a pharmacist dispenses a substitute drug product as authorized by subsection (b) of this section or interchangeable biological product as authorized by subsection (c) of this section, the pharmacist shall label the prescription container with the name of the dispensed drug product or interchangeable biological product. If the dispensed drug product or interchangeable biological product does not have a brand name, the prescription label shall indicate the generic name of the drug product or interchangeable biological product dispensed along with

the name of the drug or interchangeable biological product manufacturer or distributor.

[(g)**]** (i) A prescription dispensed by a pharmacist shall bear upon the label the name of the drug or interchangeable biological product in the container unless the prescribing practitioner writes "DO NOT LABEL", or words of similar import, on the prescription or so designates in an oral or electronic transmission of the prescription.

[(h)**]** (j) Neither the failure to instruct by the purchaser as provided in subsection (b) of this section nor the fact that a sign has been posted as provided in subsection **[**(d)**]** (f) of this section shall be a defense on the part of a pharmacist against a suit brought by any such purchaser.

[(i)**]** (k) Upon the initial filling or renewal of a prescription that contains a statistical information code based upon the most recent edition of the International Classification of Diseases indicating the prescribed drug is used for the treatment of epilepsy or to prevent seizures, a pharmacist shall not fill the prescription by using a different drug manufacturer or distributor of the prescribed drug or interchangeable biological product, unless the pharmacist (1) provides prior notice of the use of a different drug or interchangeable biological product manufacturer or distributor to the patient and the prescribing practitioner, and (2) obtains the written consent of the patient's prescribing practitioner. For purposes of obtaining the consent of the patient's prescribing practitioner required by this subsection, a pharmacist shall notify the prescribing practitioner via electronic mail or facsimile transmission. If the prescribing practitioner does not provide the necessary consent, the pharmacist shall fill the prescription without such substitution or use of a different drug or interchangeable biological product manufacturer or distributor or return the prescription to the patient or to the patient's representative for filling at another pharmacy. If a pharmacist is unable to contact the patient's prescribing practitioner after making reasonable efforts to do so, such pharmacist may exercise professional judgment in refilling a prescription in accordance with the provisions of subsection (b) of

section 20-616. For purposes of this subsection, "pharmacy" means a place of business where drugs and devices may be sold at retail and for which a pharmacy license was issued pursuant to section 20-594, including a hospital-based pharmacy when such pharmacy is filling prescriptions for employees and outpatient care, and a mail order pharmacy licensed by this state to distribute in this state. "Pharmacy" does not include a pharmacy serving patients in a long-term care facility, other institutional facility or a pharmacy that provides prescriptions for inpatient hospitals.

(l) Not later than five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific biological product provided to the patient, including the name of the biological product and the manufacturer of the biological product. The entry shall be made in a manner that is electronically accessible to the prescriber through one of the following means: (1) An interoperable electronic medical records system, (2) an electronic prescribing technology, (3) a pharmacy benefit management system, or (4) a pharmacy record. Entry into an electronic medical records system is presumed to provide notice to the prescriber. The pharmacist may communicate the biological product dispensed to the prescriber using facsimile, telephone or electronic transmission, provided such communication shall not be required when there is no federal Food and Drug Administration approved interchangeable biological product for the product prescribed or when a refill prescription is not changed from the product dispensed on the prior filling of the prescription.

[(j)**]** (m) The commissioner, with the advice and assistance of the commission, shall adopt regulations, in accordance with chapter 54, to carry out the provisions of this section."

This act shall take effect as follows and shall amend the following sections:		
Sec. 501	*October 1, 2016*	20-619